

## **REMARKS**

Claims 4, 10, and 17 are pending in the present application. Claim 4 has been amended. Applicants note that all amendments of Claims presented herein are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),<sup>1</sup> and without waiving the right to prosecute the amended Claims (or similar Claims) in the future.

### **I. Specification**

The Examiner states that the Applicant's attempt to incorporate subject matter into the application by reference to GenBank Accession No. X62841 (page 67) is ineffective as the words "incorporate" and/or "reference" have been omitted (37CFR § 1.57(b)). Additionally, the Examiner states that the Applicant's reference to the Kv3.4 nucleic acid is ineffective because the sequence appears to be "essential material" (MPEP 608.01(p)). Applicants respectfully disagree. Applicants note that the nomenclature "incorporate" and/or "reference" are not needed, as the spirit of MPEP 608.01(p) states under Section I. Incorporation by Reference, that incorporation by reference practice is used to provide the public with a patent disclosure that minimizes the public's burden to search and obtain copies of documents that might not be readily available to the public. MPEP 608.01(g) and corresponding 37CFR § 1.71(a) state that the detailed description of the invention must be such that any person skilled in the art or science of the invention is able to make and use the invention without undue experimentation. Further, 37 CFR § 1.57(c)(1) states that "essential material" is material that is necessary to provide a written description of the claimed invention in such terms to enable any person skilled in the art to make and use the invention.

Since 1992, GenBank®, a governmental database located at the National Center for Biotechnology Information (NCBI) has allowed worldwide public access to all nucleotide and protein sequences deposited there by scientists, including supporting bibliographic and biological information. Indeed, NCBI was created by Congress in 1988 and specifically charged with developing automated information systems to support molecular biology and biotechnology for

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<sup>1</sup> 65 Fed. Reg. 54603 (Sept. 8, 2000).

public use. This database is known and highly used by people worldwide to access sequence information, including scientists skilled in the art of the present invention. Therefore, the sequence referred to in GenBank Accession No. X62841 is publicly available and readily accessible by those skilled in the art. By stating the GenBank Accession No. X62841, the Applicants have enabled any person skilled in the art to make and use the invention, therefore reference to GenBank Accession No. X62841 is effective. Regardless, the Applicants herein place the nucleotide sequence for X62841 into the specification by amendment. This amendment is not new matter, as the sequence of X62841 was publicly known and was cited in the application. Applicants respectfully request that the Examiner withdraw the rejection in this regard.

The Examiner states that Claims 4, 10 and 17 are rejected as including GenBank Accession No. X62841, whereby the sequence of claimed Kv3.4 is not disclosed. Applicants respectfully disagree, for reasons previously stated. However, solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),<sup>2</sup> and without waiving the right to prosecute the amended Claims (or similar Claims) in the future, Claim 4 has been amended to include sequence locations for siRNA targets within SEQ ID NO:6. Support for these locations can be found in Example 6 (page 67) where sequence gcagaatggtgacgctaata (SEQ ID NO:3) was used and ggcagtgttgagccgaaac (SEQ ID NO:4) was used. Likewise, the specification explains that this region differs between Kv3.4a and Kv3.4C, providing a target region for siRNA that differentiates between Kv3.4a and Kv3.4c. Therefore, Applicants respectfully request that this rejection be withdrawn.

## **II. Sequence Compliance**

The Examiner states that the sequences recited on page 67 lack the required sequence identifiers. Additionally, the Examiner states that the GenBank Accession No. X62841 needs to be included in the Sequence Listing, and referred to by the proper sequence identifier. The Applicants respectfully disagree, in part. The Examiner is requested to review the previously filed (June 24, 2004) Preliminary Amendment and Response to Notice to File Missing Parts and

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<sup>2</sup> 65 Fed. Reg. 54603 (Sept. 8, 2000).

the Sequence Listing, which was filed at the USPTO in response to the Notice to File Missing Parts mailed to the Applicants on April 26, 2004. This Preliminary Amendment (page 2) amends the specification (page 67) to include sequence identification numbers. The Sequence Listing contains those sequences listed by sequence identification numbers. Therefore, Applicants have previously amended the specification to include sequence identification numbers where needed, and have submitted those sequences in the Sequence Listing. However, in view of the addition of the X62841 sequence as SEQ ID NO:6, the Applicants are providing an updated sequence listing. Please replace the paper and computer readable copy of the Sequence Listing filed June 24, 2004 with the paper and computer readable copy of the Sequence Listing attached herewith. In view of the above, the Applicants respectfully request that the Examiner withdraw this rejection.

### **III. Claim Objections**

The Examiner has objected to Claim 17 as being improperly dependent on Claim 4, as the siRNA SEQ ID NO:3 is not found in positions 2222-2283 of a Kv3.4 nucleic acid. The Applicants have amended Claim 4 as previously defined, thereby rendering the objection moot, as SEQ ID NO:3 is found within the claimed region.

### **IV. 35 USC § 112, 2<sup>nd</sup> Paragraph**

The Examiner states that Claims 4, 10 and 17 are rejected under 35 USC § 112, 2<sup>nd</sup> paragraph as allegedly being indefinite for failing to point out and distinctly claim the invention. In particular, the Examiner states the context of the claims is unclear based on the numbering 2222-2283 in Claim 4. Applicants respectfully disagree. However, without acquiescing to the Examiner's arguments and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),<sup>3</sup> and without waiving the right to prosecute the amended Claims (or similar Claims) in the future, the Applicants have amended Claim 4 to more distinctly include the sequences of the present invention.

In the Advisory Action dated 5/17/06, the Examiner indicated that "The sequences listed appear to recite the siRNA targets as either two separate regions or a region that starts with the

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<sup>3</sup> 65 Fed. Reg. 54603 (Sept. 8, 2000).

first sequence listed in the claim and ends with the second sequence listed in the claim.”  
(Advisory Action, pg. 2). The Examiner further indicated that Claim 4 does not comply with the sequence rules because it does not include a sequence identifier. The Applicants have further amended Claim 4 to distinctly recite the target region as a specific portion of SEQ ID NO:6. Therefore, the Applicants request that the rejections be withdrawn.

### CONCLUSION

All grounds of rejection of the Final Office Action of February 21, 2006 have been addressed and reconsideration of the application is respectfully requested. It is respectfully submitted that the Claims should be allowed. Should the Examiner have any questions, or if a telephone conference would aid in the prosecution of the present application, Applicants encourage the Examiner to call the undersigned collect at 608-218-6900.

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